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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,180	01/21/2004	Muthaiyyan Esakki Kannan	1276-37	4776

7590 04/24/2008
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EXAMINER

DICKINSON, PAUL W

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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04/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/762,180	Applicant(s) KANNAN ET AL.	
	Examiner PAUL DICKINSON	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-54 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10-21 and 25-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 9, 22-24 and 29-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments, filed 1/28/2008, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1, 3-7, 9, 22-24, and 29-54 are currently under consideration.

Response to Arguments

Claim Rejections - 35 USC § 102

Claims 1, 5, 29-34, 37, and 42-54 were rejected under 35 U.S.C. 102(e) as being anticipated by US 6893660 (hereafter '660) for the reasons set forth in the previous office action.

Applicant argues that the claimed composition is completely different than the composition disclosed by '660. '660 discloses a formulation wherein the low and high molecular weight polyethylene oxides are first sealed with hydroxypropyl methylcellulose and then the sealed low high molecular weight ethylene oxides are combined with a composition containing the pharmaceutically active component to form stable composition. This is in contrast to the claimed invention, wherein the pharmaceutically active component is not separated from the controlled release modifying complex. Rather, the claimed composition is obtained by mixing the pharmaceutically active agent with the controlled release modifying complex, a primary

release modifying agent such as low molecular weight polyethylene oxide, a secondary release modifying agent, such as high molecular polyethylene oxide, and an auxiliary release modifying agent such as starch, and an optional coating such as hydroxypropyl methylcellulose.

Applicant's arguments have been fully considered but are not found persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The Examiner agrees that '660 discloses a formulation wherein the low and high molecular weight polyethylene oxides (the primary and secondary release modifying agents) are first mixed with hydroxypropyl methylcellulose (the auxiliary release modifying agent) before being added to the active ingredient. This notwithstanding, the instant claims do not disclose a specific structure or order of addition, and are therefore patentably indistinct from the prior art.

The rejection of Claims 1, 5, 29-34, 37, and 42-54 under 35 U.S.C. 102(e) as being anticipated by '660 is maintained.

Claim Rejections - 35 USC § 103

Claims 1, 3-7, 9, 22-24, and 29-54 were rejected under 35 U.S.C. 103(a) as being unpatentable over US 6893660 (hereafter '660) in view of US 5585114 (hereafter

'114) in further view of US 6642276 (hereafter '276) for the reasons set forth in the previous office action.

Applicant argues that the combination of '660, '114, and '276 would not provide the claimed composition. Applicant argues that the combination of the disclosures would still result in a composition in which the release modifying excipients are sealed away from the pharmaceutically active ingredient, and not mixed with the pharmaceutically active ingredient, as instantly claimed. Applicant further argues that the Examiner does not provide any support for the combination of references. '114 does not teach that retrograded starch can be used to seal polyethylene oxide or otherwise serve as a substitute for the functionality of hydroxypropyl methycellulose. Furthermore, '276 is cited for its disclosure that macrolides such as clarithromycin are alkaline and acid sensitive. Thus, even by combining the above references, one would not arrive at the claimed invention.

Applicant's arguments have been fully considered but are not found persuasive. In response to Applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the previous office action clearly stated the reason to combine the references, and that is to produce

an improved clarithromycin pharmaceutical composition (see office action, page 6). As stated in the record, it would be obvious to substitute the acid resistant release modifying agent disclosed by '660 (hydroxypropyl methylcellulose) with the acid resistant release modifying agent disclosed by '114 (retrograded amylose). These compounds are functional equivalents and substituting one functional equivalent for another is enough to establish a prima facie case of obviousness. See MPEP § 2144.06, II.

As stated above, the instant claims do not disclose a specific structure or order of addition of the ingredients of the composition. If Applicant believes the structure of their invention makes it patentably distinct from the prior art, the claims need to reflect this feature.

The rejection of Claims 1, 3-7, 9, 22-24, and 29-54 under 35 U.S.C. 103(a) as being unpatentable over '660 in view of '114 in further view of '276 is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

April 16, 2008